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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/955,933

09/20/2001

Luba Cohen

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04/18/2008

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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

04/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,933	<b>Applicant(s)</b> COHEN, LUBA	
	<b>Examiner</b> DEBBIE K. WARE	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-11,13-17 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5, 7-11, 13-17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-2, 5, 7-11, 13-17 and 19-33 are pending.

#### ***Response to Amendment***

The amendment, request for correction of inventorship, rule 1.132 affidavits, and extension of time filed January 8, 2008, were received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5, 7-11, 13-17 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Sha et al (6280776) in view of previously cited Furhman et al.

Claims are drawn to methods for lowering risk factors and conditions in a patient selected from amongst high blood pressure, high blood glucose, high blood triglycerides, high cholesterol, hypertension, etc. Further, the methods are carried out by administering a licorice extract which is water-insoluble and free from glycyrrhizinic acid.

Sha et al teach methods for lowering risk factors and conditions in a patient selected from amongst high blood pressure, high blood glucose, high blood triglycerides, high cholesterol, hypertension, etc, see abstract. Further, the methods are carried out by administering a licorice extract, note column 4, line 16.

Furhman et al teach administering a licorice extract which is water-insoluble and free from glycyrrhizinic acid. Note page 268, column 1, "Materials" lines 1-2. An ethanol is used to extract the licorice, note page 270, column 2, only paragraph, lines 9-10. The licorice extract is disclosed to have a protective effect against LDL oxidation. The claimed licorice extract and that disclosed by Furhman et al are identical and hence has been admitted by Applicants.

The claims differ from Sha et al in that the licorice extract is not disclosed to be water insoluble and made from ethanol and hence the licorice extract is different, however, the conditions and risk factors treated as claimed are disclosed by Sha et al.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the licorice extract disclosed by Sha et al with that disclosed by Furhman et al because one of skill would have been motivated to minimize LDL oxidation in Sha et al to achieve enhanced expected results of lowering the risk factors and conditions of these problematic diseases associated with LDL oxidation. Each of the newly claimed features and limitations are disclosed by the cited prior art combination and in the absence of persuasive evidence to the contrary the claims are prima facie obvious.

### ***Response to Arguments***

Applicant's arguments filed January 8, 2008, have been fully considered but they are not persuasive. The reasoning and arguments presented by the Vaya declaration are noted and persuasive to the point that the active ingredients are different in the art. However, upon further review of the claimed subject matter it is noted that the claims are not limited to an active ingredient and the Examiner has reconsidered her initial finding during the interview of January 10, 2008, that the Vaya declaration is persuasive over the prior art. Regarding the common sense argument, one of skill would have desired to select a water insoluble extract as disclosed by Furhman et al because of the optimal effective uses that can be achieved with an insoluble extract, such as formulation which may be able to achieve a longer shelf life in an insoluble form.

Further, because Sha et al do teach that in the soluble form the glycyrrhizinic acid is the active ingredient there would be a desire to provide a water insoluble form which can also be active. An extract by definition, especially from plants, contains many unidentified active ingredients which may become relevant dependent upon the condition of the extract, (e.g. dry or wet; soluble or insoluble). The art clearly teaches that licorice extract is used to treat patients at risk for various ailments as claimed. Furthermore, Applicants claims are not limited to any active ingredient contained by the claimed licorice extract. The declaration of Michael Aviram is also noted and considered, however, Fuhrman et al is also an ethanolic extract or in other words ethanol is used to make the insoluble licorice extract.

Thus, since the same conditions are used to provide for the Fuhrman et al licorice extract it is conceivable that it can contain an unidentified active ingredient thus, providing for a licorice extract very similar to Applicants claimed licorice extract. Thus, to provide for one licorice extract having different properties for purposes of a desire to improve its utility in the art is an obvious modification of the cited prior art and one of skill would have expected successful results for using the extract of Furham et al to treat the paitents of Sha et al. Therefore, the Examiner is not persuaded by the argument that Sha et al teach away from using Fuhrman's extract simply because different active ingredients have been identified because a plant extract is useful whether its active ingredients have been identified or not.

Regarding the arguments made referencing "obvious to try" it should be noted by Applicants, that:

I. The KSR Decision and Principles of the Law of Obviousness

The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459

(1966)), but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. KSR, 550 U.S.

at \_\_\_, 82 USPQ2d at 1391. Specifically, the Supreme Court stated that the Federal

Circuit had erred in four ways: (1) “by holding that courts and patent examiners should

look only to the problem the patentee was trying to solve ” (Id. at \_\_\_, 82 USPQ2d at

1397); (2) by assuming “that a person of ordinary skill attempting to solve a problem will

be led only to those elements of prior art designed to solve the same problem” (Id.); (3) by concluding “that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try” (Id.); and (4) by overemphasizing “the risk

of courts and patent examiners falling prey to hindsight bias” and as a result applying

“[r]igid preventative rules that deny factfinders recourse to common sense” (Id. ). In KSR, the Supreme Court particularly emphasized “the need for caution in granting a

patent based on the combination of elements found in the prior art,” Id. at \_\_\_, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to

be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent

that “[t]he combination of familiar elements according to known methods is likely to be

obvious when it does no more than yield predictable results.”Id. at \_\_\_\_, 82 USPQ2d at

1395. The Supreme Court stated that there are “[t]hree cases decided after Graham

[that] illustrate this doctrine.” Id. at \_\_\_\_, 82 USPQ2d at 1395. (1) “In United States v.

Adams, . . . [t]he Court recognized that when a patent claims a structure already known in

the prior art that is altered by the mere substitution of one element for another known in

the field, the combination must do more than yield a predictable result.” Id. at \_\_\_\_, 82

USPQ2d at 1395. (2) “In Anderson ’s-Black Rock, Inc. v. Pavement Salvage Co., . . . [t]he two [pre-existing elements] in combination did no more than they would in

separate, sequential operation.”Id. at \_\_\_\_, 82 USPQ2d at 1395. (3) “[I]n Sakraida v.

AG Pro, Inc., the Court derived . . . the conclusion that when a patent simply arranges old



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elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.”

Id. at \_\_\_\_, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application

claiming the combination of elements of prior art would have been obvious. The Supreme

Court further stated that:

When a work is available in one field of endeavor, design incentives and other market

forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its

actual application is beyond his or her skill. Id. at \_\_\_\_, 82 USPQ2d at 1396.

When considering obviousness of a combination of known elements, the operative

question is thus “whether the improvement is more than the predictable use of prior art

elements according to their established functions.” Id . at \_\_\_\_, 82 USPQ2d at 1396. Finally, with respect to Applicants’ argument regarding the Examiner’s statement of Applicants admission that the licorice extract as claimed is likely the same as as Furham's extract, it is noted that there is no statement on the record that this is not in fact the case. Dr. Micahel Aviram only states that the active ingredient, glabridin, is not the same as antihypercholesterolemic drugs known to him or of anti-hypertension drugs for that matter. However, it is the licorice extract prepared by ethanolic extraction which is claimed and which is also taught by the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/  
Examiner  
Deborah K. Ware  
April 12, 2008

/David M. Naff/  
Primary Examiner, Art Unit 1657